PATENT APPLICATION

FOR

TITLE: SHOULDER GLENOID PROSTHESIS

WITH

METHODS AND TOOLS

FOR IMPLANTING IT.

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CROSS-REFERENCES TO RELATED APPLICATIONS:

US PATENT DOCUMENTS

5,080,673	Burkhead et al	Jan 14, 1992
5,489,310	Mikhail	Feb 16, 1996
5,593,448	Dong	Jan 14, 1997
5, 723,285	Cyprien, et al	Mar 3, 1998
5, 928,285	Bigliani, et al	Jul 27, 1999
6, 379,386 B1	Resh et al	Apr. 30, 2002
20030065405 A1	Amrich, et al	Apr. 03, 2003
6, 565,602 B2	Rolando et al.	May 20, 2003

FOREIGN PATENT DOCUMENT:

NON PATENT REFERENCES:

1. Anglin C. Wyss UP, Pichora DR

   Mechanical testing of shoulder prosthesis and recommendations for glenoid design

   J. Shoulder and Elbow Surg. 2000, 9: 323-31

2. Checroun AJ, MD, Hawkins C , MD, Kummer FJ , PhD, Zuckerman JD, MD

   Fit of current glenoid component designs: An anatomic cadaver study

   J J. Shoulder and Elbow Surg. 2002 • Volume 11 • Number 6

3. Nyffeler R.W., Anglin C.,Sheik R., Gerber C.

   Influence of peg design and cement mantle thickness on pull-out strength of glenoid component pegs

   J. Bone and Joint Surg. 2003, 85-B: 748-752

FEDERALLY SPONSORED RESEARCH	Not applicable
SEQUENCE LISTING OR PROGRAM	Not applicable

BACKGROUND OF THE INVENTION

0001 Replacement of diseased or injured joints is common practice in orthopedic surgery. The replacement of a shoulder joint either for arthritic disease or for fracture by an artificial device can restore function in many cases.

0002 However, total shoulder prosthetic replacement is a procedure fraught with difficulties. Among those, loosening of the glenoid implant is a most common complication. Radiolucent lines around the prosthesis are even more frequent. They can be present without pain or clinical signs of shoulder dysfunction but when progressive, they are indicative of loosening.

0003 The causes of loosening are multifactorial. They include debris-induced osteolysis in which the role of the osteoclast lineage has been evoked, deficiency of rotator cuff function, improper design resulting in eccentric loading of the implant.

0004 In designing glenoid prosthesis, a number of factors must be taken into account. Among them are the forces exerted over the inferior-superior axis, and the anterior-posterior axis. Those forces are responsible for eccentric loading of the implant. The inferior-superior forces, for instance, can induce the so-called the rocking-horse phenomenon in which of the implant is progressively pulled out of the bone. The other forces are either beneficial like the compressive component on the glenoid or inconsequential.

0005 The design of the glenoid prosthesis must follow as much as possible the anatomy of the bone. Human glenoids have in general a pear-shaped form that the design should endeavor to reproduce. A rectangular prosthesis cemented on a pear-shaped glenoid will sustain stresses leading to an unseating of the implant. Flat-backed glenoid implants have been shown experimentally to resist less easily shearing forces and eccentric loading than a curved-backed glenoid.

0006 Available glenoid implants are either all-polyethylene or metal-backed. They can be provided for cementation or with bone ingrowth structure. Cemented glenoid prostheses have either a keel or a number of pegs or both. Glenoid prostheses with keel seem to resist slightly less to experimental loosening forces than prostheses with pegs. Currently available glenoid prostheses with keel, like US patent 5,928,285, have that keel in line with the greater axis of the implant or, like US patent 6,379,386 B1, parallel to that axis. This is not the optimal position to resist to the stresses being inflicted on the glenoid implant by the inferior-superior forces. Stress=σ =F/A, F= applied forces, A= cross-sectional area. In this situation, the ratio of force acting tangentially on a limited area results in increased strain at the interfaces.

0007 The problem is to reduce the stresses on the fixation of the glenoid whether it is by peg or by keel. Ways to reduce those stresses on the fixation of a glenoid implant is either to diminish the forces being applied, which are hardly compatible with a normal shoulder function,

or to augment the area on which they are applied. One way to augment the area on which they are applied is to make the keel perpendicular to the inferior-superior forces.

0008 Loosening of implants intervenes sometimes at the implant-cement interface but most often it occurs at the bone-cement.

0009 Existing cemented glenoid implants have a high rate of radiolucent lines at the bone-cement interface that can be a foreboding to loosening. To diminish or altogether eliminate those lines, implant-cement and bone-cement interfaces must be rendered capable of withstanding stresses occasioned by activities of daily living. Other avenues like the use of certain molecules regulating negatively the activity of the osteoclast lineage might also in this regard help in the future.

00010 Improving the implant-cement interface and the bone-cement interface capability to weather loosening stresses can be done by increasing their overall contact surface. In this regard, fractal geometry is of a tremendous help.

00011 Fractal geometry comprises an alternative set of geometric principles conceived and developed by French mathematician Benoit B. Mandelbrot. Those geometric principles have been used in various fields including the medical field; see for instance US Patent 6,565,602 by Rolando et al. or the US Patent 6,287,296 by Seiler, et al among others.

00012 Fractals are geometrical figures that possess self-similarities also called invariance of scale. This means they have the same structure either on a large or on a small scale. Such figures are produced as a limit configuration of a sequence of fragments of curves. From each of these curves, the next is obtained following a defined rule. One example is the replacement of each side by a predetermined fragmentary called generative line or generator. The Koch's curve is generated by taking out one segment of an object and by replacing it by a number of segments whose length is equal to that of the removed segment.

00013 Fractals can be generated based on their property of self-similarity by means of a recursive algorithm or by various initiators and generators.

00014 One important aspect of fractal figures is their overall increase of length with the number of iterations. This is what Benoit Mandelbrot was expressing by saying that the length of a coastal line could be infinite depending on the scale on which it is measured.

00015 This remarkable attribute is of interest to the present invention. By etching at a predetermined depth a fractal figure on the medial aspect of a glenoid implant destined for cementation, the implant-cement interface is greatly increased. By the same token, engraving into the glenoid bone at a predetermined depth a fractal figure by means of a specific tool significantly increases the bone-cement interface.

00016 To illustrate this point, let us consider a curve with 5 segments of 10 mm of length (Fig 1). Now each segment is replaced with the entire

object scaled down to the length of a segment (Fig 2). Next, each segment of the new object is replaced by the new object again reduced to the appropriate scale (Fig 3).

00017 The first curve was 50 mm of length (5x10mm). The second was 82.25 mm of length (25x3.33 mm). The last curve was 231.25 mm (25x25x0.37mm). The overall length increases as the length of the individual segment diminishes. This simple fractal structure is called is a Koch curve starting with five segments.

00018 Now let us consider a given surface in which the above curves dig a trench, 3 mm deep and 1mm wide. The total surface of the walls of the trough will be 300 mm (50mmx3mmx1mmx2) for the first object. When we do the same iterations as described above, the surface is 493.50 mm^2 after the first iteration (82.25mmx3mmx1mmx2), which is a 64.5% increase. After the second iteration the total surface will be 1387.50 mm^2 (231.25mmx3mm1mmx2). This means that after only 2 iterations and for a limited area, the surface increase is of 362.5 %.

00019 The present invention eliminates the disadvantages of ordinary vertical keel glenoids, flat back glenoids and smooth back glenoids. The keel is horizontal instead of being vertical; the convex surface of the implant takes advantage of fractal geometry and the holding power of threaded pegs is used. Like in US patent 5,723,285 by Cyprien, et al, this invention has a non-conforming articular surface with 2 radiuses, the lower curvature being the largest.

00020 Method to implant the prosthesis includes use of specific tool like a pear-shaped sizing drill guide, a glenoid-marking tool and a glenoid-indentation tool.

00021 The holes drilled for the threaded pegs are made larger than the actual diameter of the pegs in order to accommodate the cement and a tap is used to cut threads into the walls of the holes. The cutting of those threads is of importance. It has been shown that smooth pegs pull out easily from the cement, while threaded pegs pull out with more difficulties and applied forces. The same thinking is valid for also creating threads in the walls of the peg's holes in which the cement will have a better hold.

00022 The bony cavity for the keels is also larger than the actual diameter of the keel in order to accommodate cement. This cavity is created by three drill holes and by progressive compaction of the bone of the central glenoid. A glenoid indentation tool is used to make a number of cuts into the walls of the cavity in order to enhance, also at this level, the bone-cement interface.

SUMMARY OF THE INVENTION

00023 The invention relates to prostheses to be fixed in the bone of the glenoid part of a human scapula in total shoulder replacement. The objective of this invention is an implant capable of withstanding the loosening forces on glenoid implants after the surgery.

00024 A pear-shaped curved-back glenoid prosthesis for cementation is described. The medial aspect of the implant has a horizontal keel, which is a keel perpendicular to the long axis of the body of the prosthesis. A threaded peg is placed above, and another threaded peg below the keel at equal distance from the center point on the inferior-superior axis. The medial aspect, as well as the horizontal keel has indented reticular structure defined following fractal geometry.

00025 A sizing drill guide with head of different sizes is used to determine the dimensions of the glenoid and subsequently to drill the appropriate holes for the keel and for the pegs. The angle between the head of the sizing drill guide can be modified to accommodate the surgeon. After an adequate reaming to expose the subchondral bone, fractal figures of predetermined depth are created with a glenoid-marking tool. The cavity for the horizontal keel is prepared by bone compaction. Next, a number of indentations are done within the cavity walls with a glenoid indentation tool. Threads are cut in the holes for the pegs with a tap.

00026 An improved bonding between the medial aspect of the implant and the cement on one hand and the between the cement and the bone on the other is achieved. Both interfaces are maximized, thereby optimizing the hold of the implant in the bone.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING

<u>Note</u>:

00027 Details of design, manufacture and procedure may be modified without departing from the spirit, intent and scope of the invention described herein.

00028 Embodiments of the invention are described in more detail in the next section using the drawings. There are shown in:

00029 FIG. 1: the initiator

00030 FIG. 2: the generator

00031 FIG. 3: a partial fractal curve after the second iteration.

00032 FIG. 4-A: a front elevational view of the lateral aspect of the glenoid implant

00033 FIG. 4-B: a front perspective view of the glenoid prosthesis

00034 FIG. 5: a side elevational view of the glenoid implant

00035 FIG. 6: a rear perspective view of the medial aspect of the implant.

00036 FIG. 7: a top elevational view of the implant

00037 FIG. 8: a side elevational view of the size-drill guide.

00038 FIG. 9: a front elevational view of the size-drill guide in position.

00039 FIG. 10-A: a side elevational view of the glenoid marking-tool.

00040 FIG. 10-B: a front elevational view of the glenoid marking-tool.

00041 Fig.11: a sectional view of the glenoid bone showing of the cavity indentation tool in the cavity of glenoid for the keel.

00042 FIG. 12: a sectional view of the glenoid bone showing of the cavity indentation tool open in the cavity of glenoid for the keel.

00043 FIG.13: a front elevational view of the articular aspect of the glenoid bone together with openings for the keel and the pegs together with a front perspective view of the prosthesis engaging in those apertures.

DETAILED DESCRIPTION OF THE DRAWINGS:

00044 Fig. 1: This figure is the initiator 20. It consists of a segmented line having two ends, each segment being of equal length and connected to at least one adjacent segment.

00045 Fig 2: This figure is the generator 22.It is obtained by replacing each segment of the initiator 20 by the initiator 20 reduced to the appropriate scale.

00046 Fig. 3: a partial fractal figure 24 obtained by replacing each segment of the generator 20 by a scaled down version of the generator 20

00047 Fig 4-A: a front elevational view of the prosthesis 100 showing its concave lateral articulating aspect 26.

00048 Fig. 4-B: a perspective view of the implant 100 showing its articular surface 26 and the horizontal keel 28 with fractal indentations 30 and holes 32 and the pegs 34 with their threads 36.

00049 Fig. 5: a side elevational view of the implant 100 with an upper curvature 38 materialized by an arc of a circle with a center O and a lower curvature 40 materialized by an arc of a circle with a center O'. A side view of the horizontal keel 28 with one peg 34 above and one peg 34 below the keel 28.

00050 Fig. 6: a rear perspective view of the convex aspect of the implant 100 showing the horizontal keel 28 with transfixing holes 32. One peg 34 is placed above and one below the keel 28. The fractal indentations 30 are visible on the implant 100 including the keel 28.

00051 Fig. 7: a top elevational view of the implant 100 with the horizontal keel 28, a peg 34, a hole 32 and the fractal indents 30 on the implant 100

00052 Fig. 8: a side elevational view of the sizing drill guide 42 with the head 44, the handle 48 with a threaded end 50 for fixation on the head 44. On each side of the head 44, there are three holes 52, in which the threaded end 50 of the handle can be fixed, depending of the surgeon preference, and a plurality of spikes 46 to stabilize the sizing drill guide in the glenoid before drilling.

00053 Fig. 9: a front elevational view of the sizing drill guide 42 in position with the head 44 of the guide, a handle 48. The head 44 has three holes 54 on a horizontal line, destined for the cavity 72 of the keel 28, and two drill holes 56 for the peg 34 of implant 100.

00054 Fig. 10-A: a side elevational view of the glenoid-marking tool 58 showing a handle 62, a head 60 with a cutting blades 66 and a centering tip 64 for introduction in the cavity 72 for the keel 28.

00055 Fig. 10-B: a front elevational view of the glenoid-marking tool 58 showing a head 60 with a centering tip 64 and cutting blades 66 on a substantially reticular pattern.

00056 Fig.11: a sectional view of the glenoid bone 70 along its major axis showing taped holes 78 destined for the pegs 34, a cavity 72 destined for the horizontal keel 28 and the cavity indentation tool 68 with blades 74 and handles 76.

00057 Fig.12: a sectional view of the glenoid bone 70 along its major axis showing taped holes 78 destined for the pegs 34, a cavity 72 destined for the horizontal keel 28 and the cavity indentation tool 68 open with the blades 74 and the indentations 80 made by the tool 68.

00058 Fig 13: an elevational view of the lateral aspect of the glenoid bone 90 with the cavity 72 for the horizontal keel 28 and the holes 78 for the pegs 34 and an oblique view of the implant 100 showing its articular surface 26 and the horizontal keel 28, the pegs 34, the prosthesis being positioned for implantation.